

nonasal SCC (30% of total cost of care). The lifetime cost of managing annual incident SCCHN cases was estimated to approximate \$976 million. **CONCLUSION:** This study found that tumor stage and location are useful predictors of increased treatment costs. The results suggest that prevention and early detection are critical in reducing the treatment costs of SCCHN.

PCN28

DETECTING RECURRENT PAPILLARY OR FOLLICULAR THYROID CANCER IN CLINICAL PRACTICE: NEED FOR A CHANGE?

Hoofst L, Hoekstra OS

University Hospital Vrije Universiteit, Amsterdam, Netherlands

OBJECTIVES: Patients with thyroid carcinoma (TC) can present a diagnostic dilemma when elevated tumormarkers (thyroglobulin, Tg) suggest relapse but whole body 131-iodine scanning (131I WBS) is negative. Then, battery of imaging modalities is available. In recent years, positron emission tomography has been proposed as an effective and comprehensive staging procedure. To estimate the effort and yield of present clinical practice, we performed a retrospective study. **METHODS:** From our Tg database we identified all TC patients, and included those with elevated Tg levels (>1.5 pmol/l on thyroid hormone medication) after ablation with 131I, between 1-5-96 and 1-1-98, and recorded the applied diagnostic work-up. **RESULTS:** Tg data were identified from 116 patients with TC. Twenty met the inclusion criteria, 18 of which (90%) had a complicated work-up. Recurrent disease was confirmed in 16. The mean number of imaging tests required to arrive at a clinical conclusion was 5 (range 3–9), within a mean period of 18 months. Since 1997, PET has been performed in 15 patients with negative or equivocal high dose 131I WBS (8 positive and 7 negative scans). Tumor sites first disclosed by PET were found in 5 patients. **CONCLUSIONS:** The current diagnostic trajectory in the majority of the patients with elevated Tg and negative 131I WBS proved to be protracted and complicated. Even though prognosis may not necessarily be adversely affected by this delay, patient anxiety is a considerable problem. FDG-PET may solve clinical problems in some of these patients, but the currently available evidence does not allow for implementation of a routine diagnostic algorithm.

CARDIOVASCULAR DISEASE**PCV1**

A COST-EFFECTIVENESS ANALYSIS OF CLOPIDOGREL VERSUS ASPIRIN AS PREVENTION OF ISCHEMIC EVENTS IN PATIENTS WITH ESTABLISHED PERIPHERAL ARTERY DISEASE

Decerbo MC, Baroletti SA, Isopo S, Silva M, Talati DK

Northeastern University, Boston, MA, USA

OBJECTIVES: Since becoming widely recognized for its antithrombotic effects in the 1970s, aspirin has become first-line antiplatelet therapy across most patient populations. However, newer data suggests that clopidogrel is more effective than aspirin for prevention of ischemic events in peripheral artery disease (PAD) patients. In this analysis, a decision analytic model was constructed in order to evaluate the cost-effectiveness of clopidogrel versus aspirin as prevention of ischemic events in patients with established PAD. **METHODS:** Data on the probability of ischemic events was extracted from the PAD subgroup of the CAPRIE trial, in which event rates for clopidogrel and aspirin were 3.71% and 4.86%, respectively. Costs included in this analysis were obtained from the medical literature. **RESULTS:** In the base case analysis, the expected cost of treatment over a one-year time frame with clopidogrel and aspirin was \$2075 and \$1088, respectively. Furthermore, to effectively treat one patient, it would cost \$2155 with clopidogrel and \$1144 with aspirin. An incremental cost-effectiveness analysis concluded that one additional event of vascular death, MI, or ischemic stroke will be prevented with clopidogrel at an additional one-year cost of \$85,826. A univariate sensitivity analysis demonstrated that aspirin must have ischemic event rates greater than 13% for clopidogrel to be the preferred option based solely on cost. Furthermore, in order for clopidogrel to be considered cost-effective with an event rate of 3.71%, aspirin must have an event rate of 11.48%, a rate 2.4 times greater than was observed in the CAPRIE trial. **CONCLUSIONS:** The result of this analysis concluded that it would cost a third-party payer an extra \$85,826 to effectively treat one additional patient over a one-year period when using clopidogrel instead of aspirin. This cost can play a major role in the decision of appropriate antiplatelet therapy used to treat PAD patients in the prevention of ischemic events.

PCV2

VENOUS THROMBOEMBOLIC (VTE) COMPLICATIONS FOLLOWING MAJOR ORTHOPEDIC SURGERY: FREQUENCY AND ECONOMIC CONSEQUENCES IN HOSPITAL

Gabriel S¹, Dinet J¹, Dispot T², Radal C²

¹Sanofi-Synthelabo, Bagneux, France; ²Medcost, Paris, France

OBJECTIVES: The risk of VTE disease in patients undergoing major orthopedic surgery (MOS) has extensively been studied in randomised clinical trials and more recently in cohort studies. Our objective was to estimate the risk of VTE disease in a much larger population and to calculate its economic consequences in hospital. **METHODS:** We conducted a retrospective study of the risk of occurrence and associated costs of VTE complications (including deep vein thrombosis (DVT) and pulmonary embolism (PE)) in patients undergoing MOS (including hip replacement, hip fracture and knee replacement). Data were obtained from the National inpatient Diagnosis Related Group (DRG) data base with ex-

haustive information concerning all the patients having undergone MOS in the year 1998 in France. These patients were stratified based on the presence or absence of a listed secondary diagnosis of DVT or PE. Length of stay in hospital and cost of inpatient care were then compared between patients with and without secondary diagnosis of VTE. **RESULTS:** 105,952 hospital stays, 37,034 and 58,135 were respectively recorded for hip replacement, knee replacement and hip fracture. Rates of VTE were recorded to be 1.4% and 2.6% for hip replacement and knee replacement respectively. For each primary Diagnosis Related Group, the length of stay was shown to be significantly higher in case of occurrence of VTE complications (19.1 days versus 15.1 for hip replacement, 18 days versus 15.2 for knee replacement, 21.4 days versus 13.8 for hip fracture). Consequently, total costs of inpatient care were substantially higher for patients with VTE complications. **CONCLUSION:** The rates of VTE observed from the National inpatient database provide information on the frequency of VTE complications after MOS in real setting. In patients undergoing major orthopedic surgery, the occurrence of VTE is associated with a longer hospital stay and higher cost of inpatient care.

PCV3

AN ANALYSIS OF THE COST OF ADVERSE EVENTS ASSOCIATED WITH THE USE OF HMG-COA REDUCTASE INHIBITORS

McBurney CR^{1,2}, Smith D²

¹Pfizer Inc., Ann Arbor, MI, USA; ²University of Michigan, Ann Arbor, MI, USA

OBJECTIVE: To perform an analysis of the cost of adverse events (AEs) associated with treatment by atorvastatin, fluvastatin, lovastatin, pravastatin, and simvastatin following NCEP low density lipoprotein-cholesterol (LDL-C) guidelines. **METHODS:** Data come from a 54-week randomized, open-label, double-blind controlled trial conducted in 158 US centers between May 1997 and January 1999. Patients (n = 3916) with or without coronary heart disease and/or peripheral vascular disease were randomized to receive atorvastatin (n = 1958), fluvastatin (n = 497), lovastatin (n = 498), pravastatin (n = 481), and simvastatin (n = 482). Inclusion criteria included elevated LDL-C for patients 18–80 years of age. Exclusion criteria included known hypersensitivity to HMG-CoA reductase inhibitors, use of selected medications, and other patient characteristics. Data were collected on AEs. **RESULTS:** A total of 9707 AEs were reported during the trial. Of these AEs, 1327 (14%) were related to the use of study medications. Related AEs involved the digestive system (387, 29%), musculoskeletal system (356, 27%), central nervous system (269, 20%), skin (124, 9%), abnormal laboratory values (68, 5%), respiratory system (40, 3%), urogenital system (25, 2%), cardiovascular system (24, 2%), and miscellaneous (35, 3%). The 1327 medication related AEs were associated with the use of 1384 medical services. Many AEs were

treated at scheduled study visits (239, 18%) and did not involve additional costs. Additional medical services typically consisted of physician office visits. There was one hospitalization (gastroenteritis). Costs of AEs were measured at Medicare payment rates—a third party perspective. The average cost of treating AEs were similar among study arms: atorvastatin \$27.78, fluvastatin \$31.78, lovastatin \$26.58, pravastatin \$25.17, and simvastatin \$32.58 (no differences were significant at $p < 0.1$). **CONCLUSIONS:** Results suggest that the cost associated with adverse events related to study medications did not vary significantly among HMG-CoA reductase inhibitors used to treat patients with elevated cholesterol levels.

PCV4

ASSESSING QUALITY OF LIFE IN PATIENTS SIX MONTHS AFTER A MYOCARDIAL INFARCTION USING THE SF-12

McBurney CR^{1,2}, Erickson SR², Kline-Rogers EM², Cooper JV², Mani OCM², Eagle KA²

¹Pfizer Inc., Ann Arbor, MI, USA; ²University of Michigan, Ann Arbor, MI, USA

OBJECTIVES: To assess patients' quality of life (HQL) post-myocardial infarction and to identify related variables. **METHODS:** Patients admitted to the University of Michigan Medical Center with diagnosis of MI were identified consecutively and prospectively from October 1999 to May 2000. Clinical data were obtained retrospectively from medical records. Six months after discharge, patients were administered the Short Form-12 (SF-12), via telephone, to determine physical (PCS-12) and mental (MCS-12) functional status. **RESULTS:** Complete information was obtained from 148 patients. The mean age of patients was 64.7 years (± 13.2) and 79.1% were male. The mean PCS-12 scores were 35.4 (± 9.12), and the mean MCS-12 scores were 51.6 (± 10.01). The median PCS-12 scores were significantly lower in patients with an ejection fraction (EF) $< 40\%$ (31.9 versus 38.4 for EF $\geq 40\%$, $p = 0.02$), and prior MI (31.2 versus 38.5 without a history of MI, $p = 0.01$), congestive heart failure (CHF) (32.6 versus 37.4 without a history of CHF, $p = 0.03$), renal insufficiency (27.9 versus 37.7, $p = 0.003$), or peripheral vascular disease (29.4 versus 38.2 without a history of PVD, $p = 0.004$). The median MCS-12 scores were significantly lower for patients under 65 years of age (49.6 versus 57.4 for patients ≥ 65 years of age, $p = 0.001$) and with a history of coronary artery bypass graft (CABG) (60.1 versus 54.7 without history of CABG, $p = 0.01$). There were no differences detected between gender, type of MI, diabetes, hypertension, angina, or smoking. **CONCLUSIONS:** HQL scores were lower for patients post-MI with various comorbidities. Physical scores were significantly lower for patients with low EFs, prior MI, or CHF. Mental scores were significantly lower for patients < 65 and those not having already undergone CABG surgery. Post-MI, particular attention should be paid to these patients. Further